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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,572	04/27/2006	Hee Young Lee	1114.003	2878
21176 7590 08/20/2008 SUMMA, ALLAN & ADDITON, P.A. 11610 NORTH COMMUNITY HOUSE ROAD SUITE 200 CHARLOTTE, NC 28277				
EXAMINER DOUKAS, MARIA E				
ART UNIT		PAPER NUMBER		
4166				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/595,572

Applicant(s)

LEE, HEE YOUNG

Examiner

MARIA E. DOUKAS

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☒ Claim(s) 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 April 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Information Disclosure Statement

The listing of references in the Search Report is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

1. Claim 13 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,779,383 to Ayres (Ayres).

In Reference to Claim 1

A syringe piston without a shaft (piston 40), used in fat transplantation (Based on MPEP §2111.02, "During examination, statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior

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art.” Since the intended use does not result in structural difference, there is no patentable distinction between the claimed invention and prior art.), disposed in a syringe-shaped cylindrical vessel (container 12), comprising:

- a piston body without the shaft (piston 40, Figures 1,2,5);

- a packing (sealing rings 50) coupled with an outer surface of the piston body to form a seal between the piston body and the syringe-shaped cylindrical vessel (col. 4, lines 4-10);

- a free oil discharging hole (annular recess 80) communicated with the front side and the rear side of the piston body;

- an opening and closing device (diaphragm 44) for opening and closing the free oil discharging hole (col. 4, lines 18-38); and

- a filtering device (filter element 60) disposed in a passage (Figure 5) through which free oil is discharged to filter fat and pass the free oil (Based on MPEP §2111.04, “Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure.” Since the structure of Ayres is capable of filtering fat and passing free oil, there is no patentable distinction in structure between Ayres and the claimed invention).

In Reference to Claim 2

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The syringe piston used in fat transplantation as set forth in claim 1 (see rejection of claim 1 above), further comprising a weight (metal insert 52) for increasing a total weight of the syringe piston (col. 3, lines 60-63; col. 4, lines 49-56).

In Reference to Claim 3

The syringe piston used in fat transplantation as set forth in claim 2 (see rejection of claim 2 above), wherein the weight takes the form of a metal ring (tubular metal insert 52) coupled with the rear side of the piston body (Figure 5; col. 3, line 59-col. 4, line 4, whereby the insert lies within the annular recess of the piston and will therefore be coupled to the rear side of the piston body).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres in view of U.S. Patent No. 3,931,018 to North, Jr. (North).

In Reference to Claim 4

Ayres teaches the syringe piston used in fat transplantation as set forth in claims 1 and 2 (see rejection of claims 1 and 2 above), but fails to teach wherein the filtering

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device comprises a net filter having a pore diameter of 10 μm to 100 μm . North teaches a cylindrical filter member 12 having a pore diameter of 50 μm or less (col. 2, lines 27-29) in order to deny passage of solid and semi-solid particulate material having a spherical diameter of greater than about 50 microns (col. 2, lines 19-22). It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the filter element 60 of Ayres with the filter member of North in order to deny passage of solid and semi-solid particulate material having a spherical diameter of greater than about 50 microns, as explicitly taught by North. Since the claimed range of 10 μm - 100 μm overlaps with the range taught by North, a *prima facie* case of obviousness exists (See MPEP §2144.05).

6. Claims 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres in view of North as applied to claim 4 above, and further in view of U.S. Patent No. 5,549,816 to Harp (Harp).

In Reference to Claim 5

Ayres in view of North teaches the syringe piston used in fat transplantation as set forth in claim 4 (see rejection of claim 4 above), but fails to teach wherein the filter is coupled with a filter groove formed in the front end of the piston body, the filter groove is closed by a cap having a thread and a plurality of holes penetrating the front and rear sides thereof to pass the free oil so that the filter is replaced by releasing the cap. Harp teaches a filter (filter media 20) coupled with a filter groove (threads 16C) formed in the

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front end of the piston body (lower end 16A), the filter groove is closed by a cap (cap 18) having a thread (col. 2, lines 62-63) and a plurality of holes (apertures 18A) penetrating the front and rear sides thereof (Figure 1) in order to separate the piston from a barrel without damaging the filter media thereby enabling the filter to be re-usable and changed at any time by releasing the cap (col. 3, lines 28-33).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have substituted the closure 14 of Ayres with the cap 18 of Harp, as well as modified the piston 40 of Ayres to be threaded to engage the cap. The filter of Ayres was substituted with the disk shaped filter of North (see rejection of claim 4 above), and it would have been obvious to one having ordinary skill in the art at the time of the invention to enclose the filter within the cap 18 of Harp and the modified piston 40 of Ayres in order to separate the piston from a barrel without damaging the filter media thereby enabling the filter to be re-usable and changed at any time by releasing the cap, as explicitly taught by Harp.

In Reference to Claim 6

Ayres in view of North and further in view of Harp teaches the syringe piston used in fat transplantation as set forth in claim 5 (see rejection of claim 5 above). Harp teaches the cap 18 includes a protrusion in the front side of the cap (Figure 1 as the front of the cap with the apertures bulges outward). Harp also teaches the protrusion will engage with the front side of the cylindrical vessel as the piston is forced through the barrel 12 (col. 3, lines 1-6) thereby allowing the cap to engage with the front of the

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barrel. When the cap of Harp is substituted into the device of Ayres modified by North as described in rejection of claim 5 above, the front protrusion of the cap will be capable of engaging with the front side of container 12 of Ayres.

7. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres in view of U.S. Patent No. 5,316,445 to Snetting (Snetting).

Ayres teaches the syringe piston used in fat transplantation as set forth in claims 1 and 2 (see rejection of claims 1 and 2 above) wherein the free oil discharging hole includes a plurality of holes (apertures 42) penetrating the front end of the piston body and the rear end of the piston body (Figure 4), but fails to teach the opening and closing device comprises: a packing for covering the rear end of the piston body; and a closing screw for fixing the packing. Snetting teaches a packing (washer 56) for covering the rear end of the piston body (piston 20), and a closing screw (threaded fastener 54; col. 1, lines 42-43) for fixing the packing (col. 1, lines 41-46) in order to secure a piston seal 52 against the piston body (col. 1, lines 45-46) and also to enable the piston seal 52 to be detached from the piston body via an Allen wrench or key so that it can be replaced (col. 2, lines 24-34).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the piston of Ayres to include a packing and closing screw as taught by Snetting that can be mounted within the annular recess 80 of Ayres in order to secure a piston seal against the piston body and also to enable the piston

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seal to be detached from the piston body via an Allen wrench or key so that it can be replaced as explicitly taught by Snetting.

8. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres in view of North as applied to claim 4 above, and further in view of Snetting.

Ayres in view of North teaches the syringe piston used in fat transplantation as set forth in claim 4 (see rejection of claim 4 above), wherein the free oil discharging hole includes a plurality of holes (apertures 42) penetrating the front end of the piston body and the rear end of the piston body (Figure 4), but fails to teach the opening and closing device comprises: a packing for covering the rear end of the piston body; and a closing screw for fixing the packing. Snetting teaches a packing (washer 56) for covering the rear end of the piston body (piston 20), and a closing screw (threaded fastener 54; col. 1, lines 42-43) for fixing the packing (col. 1, lines 41-46) in order to secure a piston seal 52 against the piston body (col. 1, lines 45-46) and also to enable the piston seal 52 to be detached from the piston body via an Allen wrench or key so that it can be replaced (col. 2, lines 24-34).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the piston of Ayres to include a packing and closing screw as taught by Snetting that can be mounted within the annular recess 80 of Ayres in order to secure a piston seal against the piston body and also to enable the piston

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seal to be detached from the piston body via an Allen wrench or key so that it can be replaced as explicitly taught by Snetting.

9. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres in view of U.S. Patent No. 3,970,565 to Ahlstrand (Ahlstrand).

Ayres teaches the syringe piston used in fat transplantation as set forth in claims 1 and 2 (see rejection of claims 1 and 2 above), wherein the filtering device (filter element 60) comprises a cap (closure 16) for sealing the front side of the free oil discharging hole (closure 16 prevents fluid from entering container 12 and therefore is capable of performing the intended use of sealing the front side of annular recess 80). Ayres fails to teach an outer filtering circumference disposed in the piston body to maintain a predetermined gap between the piston body and the inner circumference of the cylindrical vessel such that fat is filtered and the free oil passes therethrough; and a through-hole formed between the outer filtering circumference and the packing and communicated between the free oil discharging hole of the piston body and cap.

Ahlstrand teaches an outer filtering circumference (formed by lip 13 that forms a seal with tube 10: col. 2, lines 54-56) disposed in the piston body (piston 12) to maintain a predetermined gap between the piston body and the inner circumference of the cylindrical vessel (tube 10) (Figure 1 shows there is a gap formed between the piston body and tube due to the presence of lips 13 and 14). Ahlstrand also teaches slots 16 around the wall 15 of the piston which enables fluid to flow past the lip 13, through the

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gap formed between the piston body and tube, and into the piston in order to provide phase separation (col. 3, lines 37-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the piston of Ayres to include a filtering circumference in the shape of a lip as taught by Ahlstrand that can form a seal with the container 12 of Ayres. Also, it would have been obvious to have modified the piston 40 of Ayres to include slots through the outer wall 48 to provide a through-hole that communicates with the annular recess 80 and is located between the lip and sealing rings 50. These modifications would provide the predetermined gap between the piston body and container and provide communication between the closure 16 and annular recess 80, as after fluid enters the container through a cannula inserted in closure 16 it will travel through the gap formed by the addition of the lip to the piston of Ayres and enter the slots of the piston walls to access the annular recess in order to provide phase separation, as explicitly taught by Ahlstrand. (Based on MPEP §211.04, "Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure." The structure is capable of filtering fat from free oil instead of filtering blood and therefore there is no patentable distinction between the claimed invention and prior art).

10. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres in view of Ahlstrand as applied to claim 9 above, and further in view of U.S. Patent No. 4,800,020 to Savas (Savas).

Ayres in view of Ahlstrand teaches the syringe piston used in fat transplantation as set forth in claim 9 (see rejection of claim 9 above). It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the size of the lip diameter on the piston body to enable the gap size to range from 10 μm to 100 μm (see MPEP §2144.04) in order to match gap size with the viscosity of the material to be filtered as taught by Savas (col. 4, lines 59-61).

11. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres in view of Snetting as applied to claim 7 above, and further in view of Ahlstrand .

Ayres in view of Snetting teaches the syringe piston used in fat transplantation as set forth in claim 7 (see rejection of claim 7 above), wherein the filtering device comprises a cap (closure 16) for sealing the front side of the free oil discharging hole (closure 16 prevents fluid from entering container 12 and therefore is capable of performing the intended use of sealing the front side of annular recess 80). Ayres in view of Snetting fails to teach an outer filtering circumference disposed in the piston body to maintain a predetermined gap between the piston body and the inner circumference of the cylindrical vessel such that fat is filtered and the free oil passes

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therethrough; and a through-hole formed between the outer filtering circumference and the packing and communicated between the free oil discharging hole of the piston body and cap.

Ahlstrand teaches an outer filtering circumference (formed by lip 13 that forms a seal with tube 10: col. 2, lines 54-56) disposed in the piston body (piston 12) to maintain a predetermined gap between the piston body and the inner circumference of the cylindrical vessel (tube 10) (Figure 1 shows there is a gap formed between the piston body and tube due to the presence of lips 13 and 14). Ahlstrand also teaches slots 16 around the wall 15 of the piston which enables fluid to flow past the lip 13, through the gap formed between the piston body and tube, and into the piston in order to provide phase separation (col. 3, lines 37-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the piston of Ayres in view of Snetting to also include a filtering circumference in the shape of a lip as taught by Ahlstrand that can form a seal with the container 12 of Ayres. Also, it would have been obvious to have modified the piston 40 of Ayres to include slots through the outer wall 48 to provide a through-hole that communicates with the annular recess 80 and is located between the lip and sealing rings 50. These modifications would provide the predetermined gap between the piston body and container and provide communication between the closure 16 and annular recess 80, as after fluid enters the container through a cannula inserted in closure 16 it will travel through the gap formed by the addition of the lip to the piston of Ayres and enter the slots of the piston walls to access the annular recess in order to

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provide phase separation, as explicitly taught by Ahlstrand. (Based on MPEP §211.04, "Claim scope is not limited by claim language that suggests or makes optional but does not require steps to be performed, or by claim language that does not limit a claim to a particular structure." The structure is capable of filtering fat from free oil instead of filtering blood and therefore there is no patentable distinction between the claimed invention and prior art).

12. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ayres in view of U.S. Patent No. 3,799,342 to Greenspan (Greenspan).

Ayres teaches the syringe piston used in fat transplplantation as set forth in claims 1 and 2 (see rejection of claims 1 and 2 above), wherein the free oil discharging hole has a single central hole penetrating the front end of the piston body and the rear end of the piston body (annular recess 80). Ayres fails to teach wherein the opening and closing device for opening and closing the free oil discharging hole comprises: first and second check valves disposed at the sides of the free oil discharging hole and operated by the external force; and first and second fixing covers having through-holes formed at the central portions to fix the first and second check valves to the piston body.

Greenspan teaches a plug 18 that comprises check valves (valves 26) that are operated by external force as they allow fluid flow as the plug 18 is pushed downwards within the collection tube (col. 3, lines 55-61) as well as a fixing cover (rubber disc 20) having through-holes formed at the central portion (holes 30) to fix the valves to the

piston body (plug 18, Figure 4, Figure 6). The plug of Greenspan has the attached valves and fixing cover in order to prevent suspended debris and formed elements from passing through the plug (col. 1, lines 59-63).

It would have been obvious to one having ordinary skill in the art at the time of the invention to have modified the piston 40 of Ayres to include a rubber disc with through-holes and valves as taught by Greenspan on the bottom end of the piston of Ayres, as well as to have substituted the diaphragm 44 of Ayres located on the top of the piston with another rubber disc as taught by Greenspan in order to prevent suspended debris and formed elements from passing through the plug as explicitly taught by Greenspan.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 3,954,614 (Wright) teaches a piston for filtering blood with a central slit as the through-hole. U.S. Patent No. 3,931,010 (Ayres) teaches a piston with a filtering device and an opening and closing device capable of separating blood components.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ken Bomberg can be reached on (571)272-4922. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

15 . Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD

August 15, 2008

/Fenn C Mathew/
Primary Examiner,